DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Alan H. Kaplan
Richard S. Morey
Peter R. Mathers
Kleinfeld, Kaplan and Becker
1140 Nineteenth St, N.W.
Washington, D.C. 20036

Re: Docket No. 99P-1589/CP1

Gentlemen:

Pursuant to 21 CFR 10.30(e)(2), this letter informs you that the Food and Drug Administration (FDA) is still considering the issues raised in your citizen petition, submitted on behalf of Purdue Pharma L.P., requesting that FDA recognize that new drug application (NDA) 20-932 for Roxicodone (oxycodone HCl) sustained-release tablets submitted by Roxane Laboratories, Inc., is an application covered by section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. Your petition also requests that we declare the October 26, 1998, effective approval of NDA 20-932 to be null and void.

We are still evaluating the requests made in your petition, and we will respond to your petition once this process is completed.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

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